G1B

Decrease Time

Total

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity 1)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Total amount of time to conduct a comprehensive domestic Quality System Inspection
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct comprehensive medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections and report their QSIT related time per inspection on a CGCS (Form FDA 481A). Participating districts are to submit copies of the CGCSs to HFZ-332. Also, during the period 10/1/98 - 12/31/98, QSIT investigators from LOS-DO may be participating in a TURBO EIR pilot to evaluate the use of a computer program in streamlining the preparation of FDA 483s an EIRs. Beginning the week of 1/11/99, the average time for conducting domestic QSIT inspections will be calculate using PODs data extracted from the submitted CGCSs. Because the use of TURBO EIR may impact on the total inspectional time, LOS-DO inspections involving the use of TURBO EIR will not be included in this calculation. The average time for conducting QSIT inspections will be compared to the average time* for conducting comprehensive domestic Quality System inspections using the current approach. Overall responsibility for this activity: T. Wells (HFZ-332) and G. Layloff (HFR-SW450) *Note: The average PODs reported time for conducting an inspection of a domestic medical device manufacturer using the current approach includes coverage of the Quality System Regulation as well as the Medical Device Tracking Regulation. It will therefore be necessary to factor out the average time spent covering the Tracking Regulation. This will yield the average inspectional time for conducting a comprehensive domestic Quality System inspection using the current approach. The average time spent covering the Tracking Regulation will be determined by querying Device investigators as to the time spent covering Tracking on non-QSIT inspections and also through query of HFZ-305.	
Acceptance criteria (if known)	Decrease of total inspectional time.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity will provide a direct and objective measurement of the total inspectional time using the QSIT. This activity will also provide an objective comparison of total inspectional time using the QSIT versus the current approach. The objective compariso will be limited by the need to adjust the average POD reported time for conducting an inspection using the current approach in order to factor out the time that is included for covering the Tracking Regulation.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity objectively measures th satisfaction of the stated goal.	

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[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	Total amount of time to conduct a comprehensive domestic Quality System Inspection.
Acceptance Criteria	Decrease of total inspectional time.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Of those 42 inspections, 34 involved non-TURBO EIRs. Investigators reported their QSIT inspection time for each inspection on a CGCS. A tabulations of the reported times for the 34 non-TURBO inspections and also for the 42 total inspections are attached. The average time for conducting a QSIT inspection, based on the 34 non-TURBO inspections was determined to be 56.9 hours. The average time for conducting a QSIT inspection, based on the 42 total inspections, was 55.2 hours. The average time for conducting a non-QSIT comprehensive inspection including design controls is 98.6 hours (Using PODS baseline data for PACs 82830C and 82830D). The average time for conducting a non-QSIT comprehensive inspection is 84.8 hours (Using PODS baseline data for PAC 82830C only) This equates to a 42.3% reduction (Using PODS baseline data for PACs 82830C and 82830D) or 32.9% reduction (Using PODS baseline data for PAC 82830C only) of total inspection time when using the QSIT for conducting comprehensive inspections of domestic medical device manufacturers and involving non-TURBO EIRs. This equates to a 44.0% reduction (Using PODS baseline data for PACs 82830C and 82830D) or 34.9% reduction (Using PODS baseline data for PAC 82830C only) of total inspection time when using the QSIT for conducting comprehensive inspections of domestic medical device manufacturers and involving the total 42 Study inspections.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G1B (Activity 1)

As documented in QSIT Validation Activities G4, and O1A/B, use of the QSIT results in a comprehensive Quality System inspection of a medical device manufacturer.

During the QSIT Study a total of 42 inspections were conducted. Of those 42 inspections, 34 involved non-TURBO EIRs. As part of the QSIT Study, investigators reported their QSIT time for each inspection on a CGCS. The data are tabulated in Attachment 1 for the 34 non-TURBO inspections and also for the 42 total inspections.

The average time for conducting a QSIT inspection, based on the 34 non-TURBO inspections, was determined to be 56.9 hours.

The average time for conducting a QSIT inspection, based on the 42 total inspections, was 55.2 hours.

Since the G1B goal is expressed in terms of a **decrease** in the total time for conducting comprehensive domestic Quality System inspections, the total QSIT inspection time must be compared to the total time spent when conducting a comprehensive inspection using the current approach.

The PODS time reporting system for investigators tracks total inspection time. Time is tracked per type of inspection performed. For several years, and in accordance with the Compliance Program 7382.830 directive, investigators performing comprehensive domestic medical device inspections reported their time only using PAC 82830C.

With the 6/1/97 implementation of the design control requirements and the new Quality System regulation, investigators were directed per a 5/2/97 email from ORO (D. Dion) to report domestic inspectional time covering design controls under the separate PAC 82830D. This directive was reinforced by HFZ-305 (W. Morganstern/M. Hoban) in the 7/24/97 Monthly Conference Call for Medical Device Investigators. Additionally, the FY 98 workplan directed, "Design control requirements should be evaluated and reported on the Design Control Inspectional Strategy Report. Report all time used for evaluating design controls and completing the report against PAC 82830D."

The Compliance Program 7382.830 remains as a draft document, and has not been updated to reflect the new 82830D PAC. However, effective 6/1/97, the total time to conduct a comprehensive domestic medical device inspection became a combination of the time reported under PAC 82830C and the time reported under PAC 82830D.

Per an 11/25/98 POVAC data run, covering the period 10/1/97 – 9/30/98, the accomplished time per operation was reported as: PAC 82830C 84.8 hours; PAC 82830D 13.8 hours. This totals 98.6 hours and reflects the time spent to conduct a comprehensive domestic medical device inspection including design controls.

The PAC 82830C time also includes the time spent covering the Tracking Regulation. Based on a 12/18/98 email response to a 12/17/98 email query of HFZ-305, discussions with QSIT Team investigators, the limited number of firms subject to the Tracking Regulation and the limited coverage during inspections, the average time spent covering the Tracking Regulation per total comprehensive inspections conducted annually was estimated to be less then 1 hour per inspection. Therefore, it was not necessary to factor out any time from the above 84.8 hours (PAC 82830C).

TOTAL QSIT INSPECTION TIME
(Non-TURBO EIRs)

Inspection Code	Hours	Inspection Code	Hours	Inspection Code	Hours
1A1	80	2A1	33	3A1	36
1A2	80	2B1	63	3A2	27.5
1A3	130	2B2	107	3A4	35
1A4	82	2B3	60	3B1	40
1B1	70	2C1	32	3B2	55
1B2	40	2C2	40	3C1	31
1B3	40	2C3	47	3C2	48
1C1	95	2C4	28		
1C2	46	2D1	30		
1C3	95	2D2	72		
1C4	96	2D3	68		
1D1	53	2D4	44		
1D2	61				
1D3	22				
1D4	49				
Total Time	1039		624		272.5
Avg. Time per District	69.3		52		38.9

Total # of inspections (Non-TURBO EIRs) 34
Average QSIT Inspection Time per inspection 56.9 hours

TOTAL QSIT INSPECTION TIME
(Including TURBO EIRs)

Inspection Code	Hours	Inspection Code	Hours	Inspection Code	Hours
1A1	80	2A1	33	3A1	36
1A2	80	2B1	63	3A2	27.5
1A3	130	2B2	107	3A3	56
1A4	82	2B3	60	3A4	35
1B1	70	2C1	32	3B1	40
1B2	40	2C2	40	3B2	55
1B3	40	2C3	47	3B3	88
1C1	95	2C4	28	3B4	60
1C2	46	2D1	30	3C1	31
1C3	95	2D2	72	3C2	48
1C4	96	2D3	68	3C3	40
1D1	53	2D4	44	3C4	38
1D2	61			3D1	28
1D3	22			3D2	24
1D4	49			3D3	50
Total Time	1039		624		656.5
Avg. Time per District	69.3		52		43.8

Total # of inspections (Non-TURBO EIRs) 42
Average QSIT Inspection Time per inspection 55.2 hours

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity 2)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a multi-part question on a Custome Satisfaction Survey
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will l mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the multi-part question, "Did use of the QSIT result in a more efficient inspection by FDA? Yes [ ] No [ ] If yes, how did this efficiency prove beneficial to your firm? Please give examples." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses affirm that use of the QSIT resulted in a more efficient inspection by FDA	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct measurement on wheth use of the QSIT approach resulted in a more efficient inspection. A more efficient inspection correlates with decrease in inspectional time.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows firms (stakeholders) to provide input into the assessment of this goal.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
2	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses affirm that the use of the QSIT resulted in a more efficient inspection by FDA.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the multi-part question: "Did use of the QSIT result in a more efficient inspection by FDA? Yes [ ] No [ ] If yes, how did this efficiency prove beneficial to your firm? Please give examples." A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 16 (84%) No 1 (5%) Other 2 (11%) *(1 response was – both Yes and No, 1 response did not provide a specific yes or no answer.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G1B (Activity 2)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Did use of the QSIT result in a more efficient inspection by FDA? Yes [ ] No [ ]
If yes, how did this efficiency prove beneficial to your firm? Please give examples.

TABULATION of RESPONSES

Form	Yes	No	Other	Comment
1	X			Being able to sample certain Quality records reduced the time needed to assess effectiveness of our major systems.
2			No response	Don't know.
3	X			Allowed to focus on limited number of areas. Did not require excessive amount of time away from day to day activities.
4			Yes and No	The QSIT was intended to be completed within one week because of the key elements. This inspection covered nine working days and 32 calendar days. The longer period of calendar days did allow our facility to respond to some 483 observations which resulted in being able to annotate the 483 with "corrected and verified" – this was beneficial to the facility.
5	X			It tied up fewer employees and took less time to cover the inspector's agenda.
6	X			QSIT resulted in the investigator spending far fewer hours in our plant. This results in less disruption to our operation.
7	X			Inspection was focused and specific to each point of the quality system.
8	X			The inspection was limited to only few days instead of the whole week.
9	X			Kept audit very directed and focused.
10	X			It allowed us to be prepared with documents that we expected the investigator to review, so less time was wasted waiting for copies of the system-level documents.
11	X			Less time required. Specific points targeted – Better representation of our quality system.
12	X			We spent less time in the audit procedure by light reviews of areas we had strengths in and emphasizing our weaknesses.
13	X			Followed questionnaires & we were prepared to answer them.
14	X			Allowed us to commit specific resources for a predictable period of time.
15	X			In just a few days – I knew what work I needed to do.
16		X		As stated in the response to #2, the inspection was very thorough and the QSIT process neither enhanced nor hindered the inspection.
17	X			Scheduling key personnel to be available and in giving us a broader view of our compliance.
18	X			Because the inspection focus was well matched with our implementation the inspection went faster.
19	X			This approach seemed to help the inspector stay on track, covering more material in a comprehensive manner.
TOTAL	16	1	2	

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity 3)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Scope and nature of the process to be followed.[2]	In order to facilitate the inspection, the QSIT directs the investigator, during the preannouncement of the inspection, to request copies of the firm's Quality Policy and high level Quality System Procedures (including management Review Procedures), Quality Manual, Quality Plan or equivalent documents to preview prior to the inspection. Such facilitation will lead towards a decrease in the total time for conducting inspections. During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will b mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the multi-part question, " Did your company receive advance notification of th inspection? Yes [ ] No [ ] If yes, were copies of records voluntarily provided to the investigator by your firm prior to the initiation of the inspection? Yes [ ] No [ ] If yes, which records were voluntarily provided? Did providing such records facilitate the inspection process? Yes [ ] No [ ] Please explain. ____ ..." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses from firms which voluntarily provided records affirm that providing such records facilitated the inspection process.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		This activity provides a direct measurement on whethe providing records prior to the initiation of the inspecti facilitated the inspection process. Such facilitation correlates with a decrease in inspectional time.
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		This pre-deployment activity allows firms (stakeholders) to provide input into the assessment of this goal.

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[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
3	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses from firms which voluntarily provided records affirm that providing such records facilitated the inspection process.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the multi-part question: "Did your company receive advance notification of the inspection? Yes [ ] No [ ] If yes, were copies of records voluntarily provided to the investigator by your firm prior to the initiation of the inspection? Yes [ ] No [ ] If yes, which records were voluntarily provided? Did providing such records facilitate the inspection process? Yes [ ] No [ ] Please explain. ___" A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. It was determined that 18 (95%) of the 19 responding firms received advance notification c the inspection. Records were voluntarily provided by 16 (89%) of those 18 firms. A total of 15 (94%) of those 16 firms stated that providing such records facilitated the inspection process. *(1 (6%) response was No. The firm explained, "Believe auditor did nc have time to review prior to inspection."*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G1B (Activity 3)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Part 1 Did your company receive advance notification of the inspection? Yes [ ] No [ ]
Part 2 If yes, were copies of records voluntarily provided to the investigator by your firm prior to the initiation of the inspection? Yes [ ] No [ ]
Part 3 If yes, which records were voluntarily provided?
Part 4 Did providing such records facilitate the inspection process? Yes [ ] No [ ]
Part 5 Please explain.

TABULATION of RESPONSES

PART 1			PART 2		PART 3	PART 4		PART 5
Form	Y	N	Y	N	Records Provided	Y	N	Comments
1	X		X		Quality Policy Manual, Quality System Procedures	X		It allowed the inspector the chance to become familiar with our entire Quality System.
2	X		X		Quality Manual	X		
3	X		X		Quality Plan, Quality Manual, MGMT Review Procedure, Internal Audit Procedure, Design Control Proc.	X		Investigator had questions already formulated upon arrival.
4		X						
5	X		X		Quality Manual, Organizational Chart, Quality System SOPs	X		The auditor was ready to start upon arrival to our facility.
6	X		**		QA manual and Management Review Procedure	X		I think it helped the investigator prepare questions.
7	X		X		Policy & Procedures Manuals	X		Placed both the inspector and the firm on the same plane and allowed specific, focused questions.
8	X		X		* Quality Manual	X		The inspector reviewed the manual before the inspection so she could ask and probe the pertinent questions.
9	X		X		Quality Business Manual		X	Believe auditor did not have time to review prior to the inspection.
10	X			X				We offered to provide documents, but the investigator declined.
11	X		X		Top level systems documents: Quality Policy, Prod. Dev. Specs., Org. Charts, etc.	X		By reviewing these doc. Prior to inspection, the inspector already had the framework to design specific areas to audit. He could target specific areas where further clarification or doc. was needed.
12	X		X		All Procedure Manuals	X		The auditor knew areas he wanted to focus on prior to his arrival.
13	X			X				
14	X		X		SOP's for Quality Accountabilities, Quality Review, Audits, Calibration, Preventive Maintenance, and Validation	X		He arrived with basic understanding of * operations.
15	X		X		Quality Manual	X		Inspector had already reviewed and saw some concerns.
16	X		X		Quality Manual/Level I	X		Providing records prior to his arrival allowed

PART 1			PART 2		PART 3	PART 4		PART 5
Form	Y	N	Y	N	Records Provided	Y	N	Comments
					Policies			the investigator an insight to our quality systems.
17	X		X		Quality Manual	X		The inspector began the audit with a good "Macro" view of our Quality System.
18	X		X		Quality System Procedures Manual	X		The inspector was familiar with our Quality System when she arrived, so it was easier to explain how the overall system is structured.
19	X		X		Quality System Manual, and all procedures for Design Control	X		Sending the Quality System Manual and the Design Control procedures seemed to facilitate the inspection in that there was no Quality System Manual review on-site. I assume this was reviewed prior to inspection. The inspector seemed knowledgeable about Design Control System when the system was reviewed.

*The name of the firm was deleted to maintain confidentiality of the response.
** A specific Yes/No answer was not provided on the form. However, the response to Part 3 identified records that had been provided. Therefore, for this survey Form a "Yes" response to Part 2 will be included in the total.

TOTALS

Did your company receive advance notification of the inspection?
Yes 18 No 1

→ If yes, were copies of records voluntarily provided to the investigator by your firm prior to the initiation of the inspection?
Yes 16 No 2

→ Did providing such records facilitate the inspection process?
Yes 15 No 1

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity4)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Responses by investigators to a question on an Evaluation Form.
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Investigators will provide input into evaluating the QSIT b completing an Evaluation Form for each QSIT inspection conducted during the Study. The effect of the use of QSIT in increasing inspectional efficiency and thus decreasing inspectional time will be determined by the following Evaluation Form question: "Did use of the QSIT result in a more efficient inspection? Yes __ No __ Comments _____ ..." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of responses affirm that the use of QSIT resulted in a more efficient inspection.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**		This activity provides a direct measurement on whethe use of the QSIT approach resulted in a more efficient inspection. A more efficient inspection correlates with decrease in inspectional time.
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.		This pre-deployment activity allows investigators (internal stakeholders) to provide input into the assessment of this goal.

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
4	Test	Responses by investigators to a question on an Evaluation Form
Acceptance Criteria	The majority of responses affirm that the use of QSIT resulted in a more efficient inspection.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. The investigators provided input into evaluating the QSIT by completing an Evaluation Form for QSIT inspections conducted during the Study. The investigator's input into the assessment of this goal was obtained through responses to the Evaluation Form question: "Did use of the QSIT result in a more efficient inspection? Yes __ No __ Comments___..." A total of 42 QSIT inspections were conducted during the Study. An Evaluation Form was submitted for each inspection. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 34 (81%) No 2 (5%) Other 6 (14%) *(2 responses were – both Yes and No, 1 response was - Not sure, and 3 responses did not provide a specific yes or no answer.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G1B (Activity 4)

INVESTIGATOR QSIT EVALUATION FORM question:

Did use of the QSIT result in a more efficient inspection? Yes __ NO __ Comments ____

TABULATION of RESPONSES

Inspection Code	Yes	No	Other	Comment	*
1A1			None	More efficient in that QSIT calls out exactly what to look at.	B
1A2	X			More efficient in these 4 areas.	B
1A3	X				B
1A4	X				B
1B1	X			I did concentrate on specific areas.	B
1B2	X			I was able to go directly to the prescribed information and not search for areas I might want to cover.	B
1B3	X			I efficiently covered the areas prescribed.	A
1C1	X			I was able to finish the inspection in a more timely fashion.	A
1C2	X				A
1C3	X			Yes, I took less time conducting this inspection using the QSIT method of inspection. It would have taken me longer to complete this inspection, if I had used the traditional method of inspection.	A
1C4	X			I spent less time conducting this inspection, than I would have spent conducting an inspection under the traditional method of inspection. If the objective was to spend less time vs. conducting a thorough inspection, then it worked.	A
1D1			None	I think the time was well spent and I don't believe I left any product problems behind. However, I believe there are additional cGMP/QSR problems that I didn't identify, which when taken in their totality could have resulted in an OAI classification. Because of that, I made a concerted effort to explain the importance of adequate internal quality audits and top management's involvement/commitment in identifying and correcting other deficiencies.	C
1D2	X				C
1D3	X				C
1D4	X				C
2A1		X		It is difficult to see the difference in this inspection. Firm did not have many of the required procedures.	A
2B1		X		I sometimes had to re-review material (procedures, complex scenarios) on issues that cut across subsystems. Lost some opportunities to apply linked and dual system review techniques that presented themselves.	C
2B2			Yes and No	In part as it established a focus, but the sequence of subsystem review was awkward and forced some re-reviews.	C
2B3			Yes and No	It does define a focus, but the sequence of review does not always fit the natural flow. Would be more efficient if allowed to follow the natural course of emerging conditions.	C
2C1	X			Not so much during the first inspection, but I suspect each inspection will become more efficient as I get more familiar with the format.	C

Inspection Code	Yes	No	Other	Comment	*
2C2	X				C
2C3	X			Helps to focus.	C
2C4	X				C
2D1	X			Mainly because QSIT simply requires a less detailed inspection. I like not having to do a Design Control report.	B
2D2	X			In terms of time - yes. In terms of consumer protection, I'm not sure about that.	B
2D3	X			More efficient – as defined by what? If just time – yes. If consumer protection – maybe not.	B
2D4	X			Quicker, but less comprehensive.	B
3A1	X				C
3A2	X				C
3A3	X				C
3A4	X			Even with the firm located approximately 2 ½ hours (one way) from the district office, I was still able to make significant observations in 3/4 focused areas. Includes an incomplete recall of two lots of orthopedic screws (misbranded) now being addressed by the firm. There still may be other problems at the firm in areas I did not cover.	C
3B1			None	Number of processes covered – 6… As mentioned above, this PMA EI covered various procedures and validations. During a non-PMA EI, not as many procedures and/or validations may be covered. Also, this was the first EI utilizing the system which could not be used to its full capabilities. The use of the floe charts did enable a functional reference system.	C
3B2	X			It is under Design Control that I have not been fully able to evaluate with the 2 EIs done so far as neither firm have utilized the full design control procedures. Specifically, under #2, paragraph 3 it states, "Review the firm's design control procedures and verify that they address the specific requirements of the regulation." All of 820.30 is to be covered for the review of the firm's DC SOP. Would it be better to use a modified DCR to utilize a checklist type review, or modify this QSIT section more?	C
3B3	X				C
3B4	X			By the end of the inspection, it was felt the firm was fully covered under the QS/GMPs utilizing the QSIT approach.	C
3C1	X				B
3C2	X				B
3C3	X				B
3C4	X				B
3D1			Not sure		A
3D2	X				A
3D3	X				A
Total	34	2	6		

* Time in position as investigator, where A = 1-5 years, B = 6-10 years, and C >10 years

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity 5)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Responses by investigators to a multi-part question on an Evaluation Form
Scope and nature of the process to be followed.[2]	In order to facilitate the inspection, the QSIT directs the investigator, during the pre-announcement of the inspection, to request copies of the firm's Quality Policy and high level Quality System Procedures (including management Review Procedures), Quality manual, Quality Plan or equivalent documents to preview prior to the inspection. Such facilitation will result in increased efficiency of the inspection and lead towards a decrease in the total time for conducting inspections. During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Investigators will provide input into evaluating the QSIT b completing an Evaluation Form for each QSIT inspection conducted during the Study. The Form will contain the multi-part question, "Was the inspection pre-announced? Yes ___ No ___ If yes, were records voluntarily provided by the firm prior to the initiation of the inspection? Yes ___ No ___ If yes were the records reviewed? Yes ___ No ___ If yes, how much time was expended to review those records? ___ Did this review increase the efficiency of the inspection? Yes ___ No ___ Comments ___ ..." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of responses affirm that the review increased the efficiency of the inspection.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct measurement on wheth reviewing records prior to the initiation of the inspection resulted in a more efficient inspection. A more efficient inspection correlates with a decrease in inspectional time.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows investigators (internal stakeholders) to provide input into the assessment of this goal.	

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[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
5	Test	Responses by investigators to a multi-part question on an Evaluation Form
Acceptance Criteria	The majority of responses affirm that the QSIT tools were useful.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. The investigators provided input into evaluating the QSIT by completing an Evaluation Form for QSIT inspections conducted during the Study. The investigator's input into the assessment of this goal was obtained through responses to the multi-part question, "Was the inspection pre-announced? Yes ___ No ___ If yes, were records voluntarily provided by the firm prior to the initiation of the inspection? Yes ___ No ___ If yes, were the records reviewed? Yes ___ No ___ If yes, how much time was expended to review those records? ___ Did this review increase the efficiency of the inspection? Yes ___ No ___ Comments ___..." A total of 42 QSIT inspections were conducted during the Study. An Evaluation Form was submitted for each inspection. A tabulation of individual responses is attached. It was determined that 38 (90%) of the 42 inspections were pre-announced. Records were provided voluntarily for review by 30 (79%) of those 38 firms. Records from at least 20 (67%) of those 30 firms were reviewed. At best, records from 28 (93%) of those 30 firms or 28 (66.7%) of the 42 total firms were reviewed. When reviews were conducted, the average time expended to review records was 4 hours. Since record review only took place, at best, only 66.7% of the time, the overall average time expended to review records was 2.7 hours. A total of 23 (96%) out of 24 responses stated the review increased the efficiency of the inspection. *(1 (4%) response was No.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G1B (Activity 5)

INVESTIGATOR QSIT EVALUATION FORM multi-part question:

Part 1 Was the inspection pre-announced? Yes ___ No ___
Part 2 If yes, were records voluntarily provided by the firm prior to the initiation of the inspection? Yes ___ No ___
Part 3 If yes, were the records reviewed? Yes ___ No ___
Part 4 If yes, how much time was expended to review those records?
Part 5 Did this review increase the efficiency of the inspection? Yes ___ No___
Part 6 Comments _____

TABULATION of RESPONSES

PART	1		2		3		4	5		6
Inspection Code	Y	N	Y	N	Y	N	Hrs.	Y	N	Comments
1A1	X		X							Slightly
1A2	X		X					X		
1A3	X		X					X		
1A4	X		X					X		
1B1	X		X		X		3	X		Somewhat, however they were not actually following these procedures so I had to spend extra time evaluating their controls.
1B2	X			X						There was not enough time to receive the records prior to the inspection.
1B3	X			X						When this inspection was pre-announced there was not enough time to receive the document by mail before starting the inspection.
1C1	X		X		X		8		X	I think the review could have been performed in the firm without any additional time spent in the inspection. I am able to concentrate better in the firm while reviewing records. I get a lot of interruptions while I am in the office.
1C2	X		X			X				I did not have time to review the records due to the scheduling problems. As it turned out, this inspection only took 2 days to complete.
1C3	X		X		X		4	X		
1C4	X		X		X		6	X		I found that covering the design control subsystem was easier, having read the SOPs prior to starting the inspection.
1D1	X		X		X		4	X		The pre-inspectional review increased the efficiency of the inspection because I did not have to devote in the plant time to review them.
1D2	X		X		X		3	X		
1D3	X		X		X		2	X		The pre-inspectional review had a minimal impact on the efficiency of the inspection because the firm is very small and did not need extensive procedures.
1D4	X		X		X		3	X		
2A1	X			X						Firm did not have documents available. Discussed with owner and decided to cover during inspection.

PART	1		2		3		4	5		6
Inspection Code	Y	N	Y	N	Y	N	Hrs.	Y	N	Comments
2B1	X			X						Records (ISO Quality manual) was obtained 1st day of the inspection and reviewed back at the office prior to continuing the inspection. (Review 6 hours) These records are high level and tend to be generic – like particularly outside the context of the firm after unique implementation. I prefer to review them in concert with review of subsystem(s).
2B2		X								
2B3	X			X						Copies of the quality manual were included with the PMA sup. Subject of this inspection and were reviewed along with PMA review prior to the inspection. Sections of the quality procedures need to be requirements during and throughout the inspection to be efficient.
2C1	X		X			X				Due to the holiday and no mail delivery on 10/13, firm couldn't get the records to me in time.
2C2	X		X		X		2	X		This definitely helped speed up the inspection.
2C3	X		X		X		4	X		But I still had questions and needed further clarifications
2C4	X		X		X		3	X		
2D1		X								This was a regulatory follow-up inspection. (W/L)
2D2	X		X		X		2	X		Quality manual. Pre-inspection review was helpful, but not a replacement for covering the procedures during the inspection.
2D3	X		X		X		2	X		Still needed to review them at the firm in light of the inspection findings.
2D4		X								Regulatory follow-up
3A1	X		X		X					Somewhat
3A2	X		X		X		5	X		Extremely
3A3	X		X							
3A4	X		X							Review of procedures, along with the factory jacket, enabled me to formulate questions/concerns of the firm's established procedures in the district office instead of expending time at the firm.
3B1	X			X						Only the manufacturing sections of the PMA were obtained from CDRH.
3B2	X			X						EI made pursuant to obtain initial recall information and per the district's 25 month list. Firm had notified --- of their recall. First 2 days of EI was spent obtaining the recall information. Personal injury delayed the continuation of the EI for two weeks.
3B3	X			X						
3B4		X								
3C1	X		X		X		8	X		
3C2	X		X		X		5	X		I felt this expedited the process & allowed me the basic understanding prior to walking into the firm.
3C3	X		X		X		4	X		
3C4	X		X		X		4	X		
3D1	X		X		X		4-6	X		Not all of the applicable records were sent upon first request.
3D2	X		X					X		

PART I	1		2		3		4	5		6	
Inspection Code	Y	N	Y	N	Y	N	Hrs	Y	N	Comments	
3D3	X		X					X			A

- Time in position as investigator, where A = 1-5 years, B = 6-10 years, and C >10 years

TOTALS

Was the inspeetion pre-announced?
Yes 38 No 4

→ If yes, were records voluntarily provided by the firm prior to the initiation of the inspection?
Yes 30 No 8

→ If yes, were the records reviewed?
Yes 20 No 2 (No response - 8)

→ If yes, how much time was expended to review those records?
4 Hours (Avg. Time reported per 19 responses)

Did this review increase the efficiency of the inspection?
Yes 23 No 1 (No response – 6)

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G1B (Activity 6)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Responses by investigators to a multi-part question on an Evaluation Form
Scope and nature of the process to be followed.[2]	The QSIT Handbook was designed to provide investigators with information on what needs to be accomplished during a comprehensive medical device inspection, how it is to be accomplished and why it needs to be accomplished. The Handbook was developed to be a useful tool for investigators that would facilitate the inspection process and thus decrease inspectional time. During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. Investigators will provide input into evaluating the QSIT b completing an Evaluation Form for each QSIT inspection conducted during the Study. The Form will contain the multi-part question, "Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling plans) useful during the inspection? Yes ___ No ___ If yes, which tools were most useful and how were they helpful?" Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of responses affirm that the QSIT tools were useful.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct measurement on wheth the QSIT tools were useful. Such usefulness indirectly correlates with a decrease in inspectional time.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows investigators (internal stakeholders) to provide input into the assessment of this goal.	

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[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
6	Test	Responses by investigators to a multi-part question on an Evaluation Form
Acceptance Criteria	The majority of responses affirm that the QSIT tools were useful.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. The investigators provided input into evaluating the QSIT by completing an Evaluation Form for QSIT inspections conducted during the Study. The investigator's input into the assessment of this goal was obtained through responses to the multi-part question: "Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling plans) useful during the inspection? Yes ___ No ___ If yes, which tools were most useful and how were they helpful?" A total of 42 QSIT inspections were conducted during the Study. An Evaluation Form was submitted for each inspection. A tabulation of individual responses is attached. Responses to the question were as follows: Yes 42 (100%) No 0 (0%)	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Rev. 2/12/99

Item # G1B (Activity 6)

INVESTIGATOR QSIT EVALUATION FORM question:

Were the QSIT tools (Handbook – Objectives, purpose/importance statements, narratives, flowcharts, sampling plans) useful during this inspection? Yes __ NO __
If yes, which tools were most useful and how were they helpful?

TABULATION of RESPONSES

Inspection Code	Yes	No	Other	Tools Most Useful and How They Were Helpful	*
1A1	X			Good amount of detail in the handbook.	B
1A2	X				B
1A3	X				B
1A4	X				B
1B1	X			QSIT Handbook, and the Turbo 483 items.	B
1B2	X			The QSIT Handbook is the most helpful.	B
1B3	X			QSIT Handbook	B
1C1	X			The handbook was very useful and very easy to use.	A
1C2	X			The inspection handbook was very easy to read and easy to follow.	A
1C3	X			I call the QSIT Handbook my bible. It is very easy to use and very helpful.	A
1C4	X			I found that the QSIT Handbook was very useful. It was very easy to read and it kept me focused.	A
1D1	X			I found myself relying on the flowcharts because they are concise and compact enough for ready reference. Then, I would go to the narrative section if I needed more detailed information	C
1D2	X			The flowcharts and sampling plans were the most useful. The sampling plans helped limit the number of records I needed to review. The simplistic format of the flowchart made it easy to reference specific areas as needed and then served as a gateway to the narrative sections if I needed additional explanations.	C
1D3	X			The flowchart was the most useful tool. Very limited use was made of the sampling plans because the firm did not have very many records for review.	C
1D4	X			The flowchart and sampling tables were most useful because they helped narrow the focus of the inspection.	C
2A1	X			I did not follow objectives in exact order, but covered all objectives – learning curve.	A
2B1	X			Helped to focus on and complete all aspects of the QSIT requirements.	C
2B2	X			I used the sampling table. It helped maintain focus. The CAPA section was useful but problematic. Helped to define the scope of my review, but the narrative suggests a wider review with more sampling then is on the Decision flow chart.	C
2B3	X			The various subsystem questions and narrative were helpful for keeping the inspection on course with QSIT requirements.	C
2C1	X			The handbook was the most useful, especially with this being my first QSIT inspection. I followed it pretty closely during the inspection.	C
2C2	X			QSIT handbook – I followed it faithfully	C

Inspection Code	Yes	No	Other	Tools Most Useful and How They Were Helpful	*
2C3	X			QSIT handbook was the most useful – it helps structure the course of the inspection.	C
2C4	X			Most useful – QSIT Handbook – specifically the narratives	C
2D1	X			I relied mainly on the objectives, then referred to the narrative as needed.	B
2D2	X			Guided the order of inspection coverage. Served as reminder of areas to cover.	B
2D3	X			List of Objectives was most helpful	B
2D4	X			Objectives list	B
3A1	X			Narrative and flowchart were most helpful – kept EI focused	C
3A2	X			Always the narrative/flowchart	C
3A3	X				C
3A4	X			The narrative and the sampling plan kept the inspection focused and timely. The sampling plan reduced the quantity of records I would have reviewed during a routine inspection. Even though the number of records were reduced, I was still able to make significant observations in the focused areas (e.g. management control, production and process controls).	C
3B1	X			The flow charts were utilized primarily after a copy of them were modified to include keywords for reference of the narrative sections for further follow up and/or clarification.	C
3B2	X			The flowchart again was found the most convenient tool for staying on track but the handbook had to be utilized more during the CAPA section to keep from deviating. The sampling plan Table 1, Confidence Level A for a 11 record sampling size was utilized on the in-process tip component record, complaint, non-compliance, in-compliance, trending, corrective action, and training record reviews. However, during P&PC, while reviewing the heat sealer validations and maintenance, I had to return to the tip component records that had already been reviewed and view several additional tip component history records to determine the extent of the deviation (FD483 #1) for all size tips as only the size 50 & 56 French were originally covered. In essence, even though the minimum no. of records were reviewed and no deviations were found for the areas originally being reviewed, you may have to return to those records under P&PC and expand on them. This should be noted under P&PC for clarification purposes. (I hope this is clear. If not give me a call.) For firms that manufacture complex devices or utilize very technical and complex manufacturing processes. I would have trouble in the P&PC Section to select only one process. As mentioned in today's telecon, the CSO should have the option of doing at least two processes if needed to verify the firm is in compliance with QS/GMPs.	C
3B3	X			Again the flowcharts were mostly used with both the flowchart and the booklet being used under CAPA	C
3B4	X			All aspects of the handbook were utilized with the flowchart being used as the main potion of the handbook with the narrative portion being used for clarification. The sampling tables were used extensively.	C
3C1	X			Narratives & flowcharts	B
3C2	X				B
3C3	X			Narratives	B
3C4	X				B

Inspection Code	Yes	No	Other	Tools Most Useful and How They Were Helpful	*
3D1	X			Flowchart is very helpful	A
3D2	X				A
3D3	X				A
Total	42	0	0		

* Time in position as investigator, where A = 1-5 years, B = 6-10 years, and C >10 years